510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY TEMPLATE

A. 510(k) Number:

K050002

B. Purpose for Submission:

To introduce a smaller version of the VITEK® 2 with new software

C. Manufacturer and Instrument Name:

bioMerieux, Inc. – VITEK®2 Compact

D. Type of Test or Tests Performed:

In vitro diagnostic test software used for identification and antimicrobial susceptibility testing of organisms

E. System Descriptions:

1. Devise Description:

The VITEK® 2 Compact System is dedicated to the identification of bacteria and yeasts and susceptibility testing of clinically significant bacteria using the VITEK® 2 Product line of cards. The system includes the VITEK® 2 Compact instrument, a computer (workstation) and printer. The system software is a component used to support the VITEK®2 Compact instrument and runs in a PC environment. The system includes an Advanced Expert System (AES) for clinical use, provides therapeutic guidance for advanced analysis of results and the detection of phenotypes. The user documentation available with the workstation software is in Adobe PDF format (Software User Manual and the Online Product information open in PDF format). The system allows the user to manage and enter patient and specimen information; interpret organism identification from biochemical test results using a set of claimed organisms/reactions; manage Quality Control (QC); view and modify configuration parameters; and create new AST card definitions, search audit history and archive reports. A bidirectional computer interface transfers results automatically to the user's laboratory information system (LIS) and to various product and patient reports.

2. Principles of Operation:

The system software is a component used to support the VITEK®2 Compact instrument and runs in a PC environment. Transmittance Optics uses visible light

to directly measure organism growth. The optics use light emitting diodes (LEDs) which produce light at the appropriate wavelengths and silicon photodetectors to capture the transmitted light.

3. Modes of Operation:

   Automated reading of growth based AST cards in cassettes. Each card is transferred from the cassette to a card loader to place into a slot on a carousel where it remains throughout its incubation. Each carousel has a capacity of 30 to 60 cards and is kept at a temperature of 35.5^{o} C. As the carousel rotates each test card moves into the reading position every 15 minutes. At the completion of the reading the card is ejected into the waste collection station.

4. Specimen Identification:

   Patient information may be entered manually or downloaded from a data management system. The instrument reads the bar code information from the cards and cassettes and automatically sends the information to the system software.

5. Specimen Sampling and Handling:

   Isolated colonies are inoculated into saline and then the density adjusted to a McFarland standard using a VITEK®2 DENSICHECK. Specimens are inoculated into test cards which are placed in a cassette.

6. Calibration:

   Self calibrating.

7. Quality Control:

   QC isolates are tested according to the type of panel used. Expected ranges are listed for each antibiotic and organism.

8. Software:

   FDA has reviewed applicant's Hazard Analysis and Software Development processes for this line of product types:

   Yes_____X___ or No_____

F. Regulatory Information:

1. Regulation section:

866.1645

2. Classification:

   Class II

3 Product code:

   LON

4. Panel:

   83 Microbiology

G. Intended Use:

1. Indication(s) for Use:

   The VITEK® 2 Compact System is intended to be used for the automated quantitative or qualitative susceptibility testing of isolated colonies for most clinically significant aerobic gram-negative bacilli, *Staphylococcus spp.*, *Enterococcus spp.*, *Streptococcus agalactiae* and *S. pneumoniae*.

2. Special Conditions for Use Statement(s):

   For prescription use.

   For testing the VITEK® 2 Systems Products

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:

   VITEK® 2 System N50510/S82

2. Comparison with Predicate Device:

Similarities		
Item	Device	Predicate
Intended Use	The VITEK® 2 Compact is intended to be used for the automated quantitative or qualitative susceptibility testing of isolated colonies for most clinically significant	The VITEK® 2 is intended to be used for the automated quantitative or qualitative susceptibility testing of isolated colonies for most clinically significant

Similarities		
Item	Device	Predicate
	aerobic gram-negative bacilli, *Staphylococcus spp.*, *Enterococcus spp.*, *Streptococcus agalactiae* and *S. pneumoniae*.	aerobic gram-negative bacilli, *Staphylococcus spp.*, *Enterococcus spp.*, *Streptococcus agalactiae* and *S. pneumoniae*.
Test Cards	64 well card with antibiotics in varying concentrations dried with a microbiological medium	same
AST CARD inoculum	Isolated colonies prepared with a DENSICHECK densitometer	same
Filling and Sealer process	Vacuum filled and automated heat seal	same
Incubation and reading	Automated, 35.5^{o}C +/- 1^{o} with automated readings every 15 minutes with 660 nm optics	same
AST analysis	Analysis of changes in growth based turbidity	same
Advanced Expert System	Yes	Yes
Waste	Automated removal of ejected test cards to waste container at end of cycle	Automated removal of ejected test cards to waste container at end of cycle

Differences		
Item	Device	Predicate
Instrument Capacity	30-60 cards	60-120 cards
Computer	HP/Compaq Windows XP Pro PC with Pentium 4 processor	IBM AIX Workstation with RISC6000 processor
Test set up	Visual Smart Carrier Test setup at Workstation downloaded to instrument	Smart Carrier Test setup programmed onto embedded programmable chip in card cassette then downloaded to instrument
Cassette	10 cards/cassette	15 cards/cassette
AST dilution preparation step and filling process	Manual dilution only with two step filling process	Automated or manual dilution with automated filling process with automated timing control
QC Results	Provides a side-by-side	No comparison of

Differences		
Item	Device	Predicate
	comparison of expected versus actual QC results	expected results versus actual QC results.

I. Special Control/Guidance Document Referenced (if applicable):

"Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA"; CLSI M7 (M100-S15) "Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically; Approved Standard"; "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

J. Performance Characteristics*:*

1. Analytical Performance:

a. Accuracy:

A challenge phase of testing was performed to confirm the agreement in results over a broad range of organisms using the AST test cards. Each organism was inoculated into 2 cards to be tested on each system at each of three sites. Overall agreement performance was >95% for gram negative organisms (n = 8,002 results) gram positive organisms (n=6480 results) and *Streptococcus pneumoniae* (n =1, 215 results). Quality control isolates were also tested a sufficient number of times on each instrument with results in the expected range in the criterion set up for the study that there would be no decrease of more than 2.5% in the rate of results falling within range from the VITEK® 2 to the VITEK® 2 Compact. Studies were performed to demonstrate that AST results are essentially equivalent when using either the VITEK® 2 or the VITEK® 2 Compact. The primary difference between the two systems is the test disposable filling and sealing process and this was demonstrated to have no significant impact on product performance.

b. Precision/Reproducibility:

A study was performed to provide the best comparison for the two systems for accuracy and precision. For accuracy the medians should agree within +/- 1 doubling dilution at a rate greater than 95% and for precision the rate of results falling within plus or minus one 2-fold serial dilution of the median of the VITEK® 2 Compact to be within 2.5% of the rate of results falling within plus or minus one 2-fold serial dilution of the VITEK® 2. These were met with no obvious suggestion of trending of an instrument bias in one direction.

c. Linearity:

Not applicable

d. Carryover:

Not Applicable

e. Interfering Substances:

Not Applicable

2. Other Supportive Instrument Performance Data Not Covered Above:

Not Applicable

K. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

L. Conclusion:

1. The submitted information in this premarket notification is complete and supports a substantial equivalence decision.